USDA

United States Department of Agriculture

Agricultural Marketing Service

STOP 0201 – Room 3071-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0201

Mr. David E. Carter
Chairman
National Organic Standards Board
10081 Yates Street
Westminster, Colorado 80031

BY FACSIMILIE & EMAIL
303-466-1782
de.carter@attbi.com

May 9, 2003

Dear Dave:

We are looking forward to attending the upcoming National Organic Standards Board (NOSB) meeting in Austin, Texas next week. We anticipate that the meeting will be productive and positive. One of our objectives for this meeting is to communicate a clear message of integrity, transparency, and creditability for the processes and actions taken by the National Organic Program (NOP).

Prior to the commencement of the Board meeting on May 13th, the Board and staff of the NOP will meet because the Board has expressed its intention to follow up on various issues that were raised during the February retreat here in Washington. At this meeting, we plan to present the issues that are outlined below, and as a courtesy, we are providing you with an advance copy of these items.

Now that the Program is no longer in the development phase, but in a combined state of rulemaking modification and enforcement, we are modifying some of our approaches to handling program-related issues to more responsibly account for actions that we take on behalf of the organic industry and the general public. This is discussed in more detail below.

1. We want to reiterate that the agenda item "Program Update" that is usually presented by either Richard or Barbara is just that – an update on program activities. It is not an invitation for debate and discussion: this is the meeting of the NOSB, not the NOP. We strongly suggest that, as chair of the NOSB, you delay discussion for a later time period and immediately proceed with the subsequent items on the agenda. We believe this is more efficient, and will result in better overall time management for a crowded agenda facing the NOSB.

2. In order to more fully demonstrate transparency in our decision process to the public, we will provide the Board, as well as all interested public parties, with a written description of our procedures and requirements for all actions taken by NOP to address issues raised by a member of the public, the Board, or by internal staff. This "decision tree" is the same process that NOP currently uses to arrive at a decision or resolution regarding the day-to-day issues that arise; it is the same

process by which we evaluate the appropriate action needed and assign a priority to the issue. All preliminary results of this process will be presented to the public (including the Board) ***prior*** to any final resolution (either rulemaking or policy statement) made by NOP. We believe this will greatly improve transparency of our decision process, result in a more inclusive public dialogue, and ultimately, generate outcomes that facilitate the success of the U.S. organic agricultural sector.

3. We ask that the Board prepare and provide a daily summary of the activities and recommendations made during the Board meeting, beginning in Austin, and for all future meetings as well. Such summaries must be agreed to by the entire Board and presented at the opening session of the following day's meeting, but no later than the conclusion of the meeting. Daily summaries are not a substitute for meeting minutes, although they should greatly facilitate an understanding of the minutes and provide a clear record of the Board's intent and actions. Minutes record what is stated at the meeting; summaries more accurately convey the intent of the Board. We have determined that this is necessary to help the NOP accurately capture (and the general public to fully understand) the intent and actions of the Board. However, while this is necessary, it is not sufficient to guarantee action on a Board recommendation. The decision tree referred to above is critical to effecting action on any recommendation, regardless of its origination.

4. Finally, we will present the Board with our expectations for the timing of future meetings, based on work that is completed within a reasonable time ahead of any scheduled meeting. This week alone, eight conference calls have been held to finish work in order for the Board to deal with various items on the agenda. Four conference calls were held in April. We do not question the legitimate discussions taking place during these calls. But the very fact that so many conference calls occur less than a week prior to a Board meeting, that has been known about for a year (and scheduled since last October), indicates that work is being left until the last minute to be completed. These delays result in time lost at meetings, materials not finished for timely inclusion in the book to be distributed and considered by all Board members, and general inefficiencies in discussing and concluding the business of the Board in a timely manner. Not insignificantly, such a large number of conference calls also drain scarce financial resources that could be more productively used by NOP.

   Therefore, we will implement a new timeframe for scheduling all future meetings to ensure that work is concluded in advance of the meeting, or risk postponing either the meeting or that work for a later meeting. Specifically, we will require that work to be deliberated by the Board at an upcoming meeting must be concluded 60 days prior to the scheduled meeting. We will inform the Board of completed TAP reviews that will be eligible for consideration by the Board (assuming all other accompanying work relating to said material is also completed). This time period provides us with sufficient time to prepare all materials for Departmental approval by appropriate officials and have adequate

notice to the public through the Federal Register. This also gives Board members sufficient time to digest all items on the agenda and will facilitate a more efficient meeting experience.

Again, we look forward to the National Organic Standards Board's first meeting in this new environment, now that implementation of the national organic standards has occurred.

Sincerely,

Barbara C. Robinson
Deputy Administrator
Transportation & Marketing Programs
Agricultural Marketing Service
U.S. Department of Agriculture

Richard Mathews
Program Manager
National Organic Program
Transportation & Marketing Programs
Agricultural Marketing Service
U.S. Department of Agriculture

United States Department of Agriculture
Agricultural Marketing Service
STOP 0264 – Room 2510-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0264

Mr. David E. Carter, Chairman
National Organic Standards Board
10081 Yates Street
Westminster, Colorado 80031

July 31, 2003

Dear Dave:

We are writing to notify the National Organic Standards Board that we are unable to accept certain NOSB recommendations regarding synthetic substances for use in organic livestock production due to information received during our statutorily required consultations with the Food and Drug Administration's (FDA). As you are aware, these consultations ensure that NOSB recommendations are lawful under the requirements of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.)*.

FDA has determined that 10 synthetic substances recommended to the Secretary by the NOSB for use in organic livestock production are not approved for use as animal medicines in food animals. The substances are: activated charcoal, bismuth subsalicylate, butorphanol, calcium borogluconate, calcium propionate, kaolin pectate, magnesium hydroxide, magnesium oxide, mineral oil, and potassium sorbate when used as a preservative in aloe vera products used as animal medicines. Attached to this letter (in facsimile form only) is a copy of FDA's response to our inquiry.

Therefore, these substances will not be included in the upcoming rulemaking on synthetic substances used in organic livestock production. Further, these substances cannot be used in livestock and livestock products to be sold, labeled or represented as organic under Subpart D of the National Organic Standards (7 CFR 205.300-311). The petitioners of these substances are also being informed of FDA's determination under separate cover.

Very shortly, we will also be sending you a subsequent letter discussing our thoughts on the overall process of materials dealing with petition, review, evaluation, and approval. We believe that this topic should be added to the agenda for the October 2003 meeting, and will send further details on this to the full Board later this summer.

Sincerely,

Barbara C. Robinson
Deputy Administrator

Richard H. Mathews
Program Manager

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 23, 2003

Mr. Authur Neal
National Organic Program Staff
USDA
Room 4008, South Building
1400 Independence Avenue, SW
Washington, DC 20250

Dear Mr. Neal:

This letter is in response to your emails to Dr. George Graber on March 25, 2003, and to Dr. Sharon Benz on April 24, 2003, that included lists of substances that the National Organic Standards Board is considering for inclusion into the National List for appropriate use in livestock production under the National Organic Program. You asked whether the Food and Drug Administration had any concerns regarding the use of the proposed substances.

The March 25, 2003, email included lists of substances under Proposals (a), (b), (c), and (d). We note under Proposal (a), it states in general that the substances are to be used as disinfectants, sanitizers, and medical treatments. Since the list did not give a specific intended use for each, we assumed it was intended for medical treatment. We have the following comments on the substances:

Proposal (a).

Activated Charcoal, vegetable sources – This is not approved by the FDA for use in animals.

Bismuth subsalicylate – This is not approved by FDA for use in animals.

Butorphanol – This is not approved for use in food animals. FDA has not determined a withdrawal since there are no food animal uses approved.

Calcium borogluconate – This is not approved by FDA for use in animals.

Calcium propionate – This is generally recognized as safe as a chemical preservative in animal feed (21 CFR 582.3221). There are no approvals for its use to treat milk fever.

Charcoal, activated – This is not approved by FDA for use in animals.

Flunixin – Flunixin meglumine is only approved for beef and nonlactating dairy cattle. The limitations state that it is not to be used in lactating or dry cows and a withdrawal period has not been established for preruminanting calves (21 CFR 520.970 and 522.970). The statement to withhold for twice the FDA withdrawal has no value and is misleading.

Kaolin pectin – This is not approved by FDA for use in animals.

Magnesium Hydroxide/magnesium oxide – It is considered generally recognized as safe as a source of magnesium in animal diets. It is not approved for any animal medical uses.

Mineral Oil - This is approved as a food additive (21 CFR 573.680) to reduce dustiness in animal feeds or mineral supplements. It cannot exceed 0.06% of the total ration. It is not approved for any animal medical uses.

Polaxalene - FDA has approved this for the treatment of bloat (see 21 CFR 520.1840 and 558.464)

Potassium sorbate – This is generally recognized as safe as a chemical preservative in animal feeds (21 CFR 582.3640). It is not approved for any animal medical uses.

Propylene glycol – This is generally recognized as safe as an animal feed ingredient (except cats, 21 CFR 582.1666 and 589.1001). While it is not approved by FDA for treatment of ketosis, we have used regulatory discretion and permitted its use as "an aid in prevention/treatment of ketosis."

Talazoline (not Talzoline) - Talazoline hydrochloride injection is approved by FDA only for use in non-food animals (see 522.2474). A withdrawal time has not been established. The statement to withhold for twice the FDA withdrawal has no value and is misleading.

Xylazine – Xylazine hydrochloride is approved by FDA only for use in non-food animals (see 522.2662). A withdrawal time has not been established. The statement to withhold for twice the FDA withdrawal has no value and is misleading.

Proposal (b)

Potassium sorbate in an Aloe Vera product as a topical treatment, external parasiticide, and local anesthetic. Potassium sorbate is generally recognized as safe as a chemical preservative in animal feeds (21 CFR 582.3640). It is not approved for any animal medical uses.

Moreover, aloe vera is not an approved drug for external treatment or anesthetic.

Proposal (c)

The following substances are proposed as feed additives.

Methioinine – This is generally recognized as safe for use in animal feeds in accordance with good nutritional practice. (21 CFR 582. 5475).

Potassium sorbate for use in an aloe vera product - Potassium sorbate is generally recognized as safe as a chemical preservative in animal feeds (21 CFR 582.3640). However, aloe vera is not an approved for use in animal feeds except as a flavoring agent not to exceed 150 ppm of the total diet.

Proposal (d)

Epinephrine is listed as the emergency treatment for anaphylactic shock. This use is not approved but the use of a 1:1000 solution is discussed in 21 CFR 500.65 as well as labeling requirements. FDA would object in animals intended for slaughter.

In addition, comments were requested on the following substances in your April 24 email to Dr. Benz:

Proteinated chelates for use in feed – Copper, zinc, magnesium, iron, cobalt, manganese, and calcium proteinates are acceptable for use in animal feed as a source of the mineral. The ingredient must meet the definition established in the Official Publication of the Association of American Feed Control Officials, No. 57.23[1].

Calcium propionate - See comment above.

Furosemide, as a medical treatment – This is approved for the use in cattle at levels of 1 to 2 mg per pound body weight for treatment of physiological parturient edema of the mammary gland (see 21 CFR 520.1010 and 522.1010). Use is limited not to exceed 48 hours post partum and has a 48 hour withdrawal period for milk and slaughter of the animal.

Mineral oil as a feed additive - This is approved as a food additive (21 CFR 573.680) to reduce dustiness in animal feeds or mineral supplements. It cannot exceed 0.06% of the total ration.

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[1] The Official Publication of the Association of American Feed Control Officials (AAFCO) may be obtained from Sharon Senesac, Assistant Secretary-Treasurer, AAFCO, P.O. Box 478, Oxford, Indiana 47971.

Atropine, as a medical treatment – Atropine sulfate should be labeled as per 21 CFR 500.55. FDA regulations provide for its use in conjunction with droperidol and fentamyl citrate injection in dogs as an analgesic and tranquilizer (21 CFR 522.800) and as an antidote for dichlorvos poisoning in swine (21 CFR 558.205) and for organophosphate poisoning in conjunction with pralidoxine chloride for dogs, cats, and horses (21 CFR 522.1862).
Moxidectin, for use as a parasiticide – This is approved by FDA to treat internal and external parasites in beef and dairy cattle at the rate of 0.5 mg per kg of body weight (see 21 CFR 524.1451). A withdrawal time has not been established for preruminanting calves. It is also approved for use in horses, not intended for food, as a parasiticide.

We remind you that only FDA-approved products should be included on the National Organic List. In addition, products are approved for certain uses and in certain species. We encourage you to review the list of drug and food additive approvals, as well as the list of substances considered generally recognized as safe in Title 21 of the Code of Federal Regulations Part 500 for the specific approvals. I hope this information is helpful.

Sincerely,

Sharon A. Benz

Sharon A. Benz, Ph.D.
Leader, Nutrition and Labeling Team
Division of Animal Feeds
Center for Veterinary Medicine

United States Department of Agriculture
Agricultural Marketing Service
STOP 0264 – Room 2510-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0264

RECEIVED AUG 1 2 2003

TO: David Carter, Chairman
National Organic Standards Board

FROM: Barbara C. Robinson, Deputy Administrator
Richard H. Mathews, Program Manager

The purpose of this memo is to discuss the process of review and approval of materials for amending the National List of approved synthetic and prohibited natural materials.

As we discussed at the May 2003 meeting of the National Organic Standards Board (NOSB), the national organic standards now carry the effect of law since full implementation on October 21, 2002. All actions taken by the National Organic Program (NOP) that are derived from NOSB recommendations which result in regulatory changes must be legally defensible, sound, and consistent in order for the organic industry and consumers to trust in the credibility of the marketing claim known as "organic" and certified by a USDA-accredited certifying agent. At that meeting, we also reminded the NOSB that materials being reviewed for the National List must be evaluated against the relevant criteria in the Organic Foods Production Act (OFPA) as well as section 205.600 of the final regulations (7 CFR Part 205).

Currently we are reviewing the Board's May decisions on materials in order to prepare a proposed rule to amend the National List. Our review of the voting forms and transcripts shows that the discussions and subsequent vote are less than clear with respect to how the materials meet the required criteria in OFPA and section 205.600.

It goes without saying the process of amending the National List is complex and arduous. And, while the decisions facing the Board will always be challenging, the process by which the Board arrives at its decisions should not be. The Board's decision process and subsequent outcomes should clearly convey how and why petitioned materials meet or fail to meet the required evaluation criteria. This will ensure full transparency to the public.

Perhaps the complexity of the process relates to the number of criteria to be considered, the fact that some overlap, and some are redundant in both the statute and the regulations. Therefore, in the interest of making this process more transparent and manageable, we intend to provide the Board with an updated and more streamlined template to use in its deliberations and decision and voting processes on materials. This template will also enhance our ability to write a legally-defensible proposed amendment to the National List. If the decision on a material cannot be explained by adherence to the various criteria required under law, NOP has no alternative but to return the material to the Board for further evaluation.

The criteria in OFPA and 205.600 boil down to three general categories which *must* be considered for any material. Those three categories are:

1. Adverse (harmful) effects on the environment or on human health;
2. Availability of suitable alternatives (organic, natural but not organic, or synthetic) that determine the necessity of the material in organic production or handling.
3. Compatibility of the material with organic practices in production or handling.

Regarding category (1), we believe the Board might consider benchmarks for evaluating the degree of adverse impacts that might cause a material to be rejected outright or that justify further review and discussion. We will provide these benchmarks for consideration by the Board when we send you the draft template for materials review and evaluation.

Regarding category (2), a review of the statute and regulations provides something akin to the hierarchy that was used for acquiring seeds for organic crop production. Thus, is there an organic substitute? Failing that, is there a natural but not organically produced substitute, and finally, another synthetic that may be less egregious than the material being considered or is approved already and added to the List?

Categories (1) and (2) are mainly empirical matters that can be addressed by reviewing technical, scientific, and economic data. Category (3) is the area in which we see the Board having the most discussion. Category (3) requires consideration by the Board, including input from the public, about the appropriateness of a material in organic production and handling. Here, we look to the Board to explicitly acknowledge how it considers "compatibility with organic production or handling." We recognize that this category will reflect the Board's attitudes, views, or other factors. Over time, this is the area most likely to change as well. Therefore, knowing that current Board decisions will influence future Boards, we believe the Board has a responsibility to clearly enunciate its views of compatibility with organic practices with respect to materials. We may offer suggestions here, but we believe this is rightfully the Board's purview to determine within the requirements of OFPA, the NOP regulation, and other applicable Federal regulations.

The results of the Board's evaluation of a material with respect to the 3 criteria groups above are required in order to proceed to amend the National List. Without this, NOP must make assumptions regarding the Board's intentions or decision making process.

An example might help explain what we mean. In the September 2002 meeting, the Board voted to allow calcium propionate to treat milk fever in dairy cattle. In May 2003, following a supplemental TAP review, the Board voted to add calcium propionate as a synthetic for use as a mold inhibitor in dry formulated herbal remedies. Part of the Board's decision rested, as best as we can determine, on the fact that it had already approved the material for use in treating milk fever. This would be satisfactory under two circumstances.

First, we do believe that when the Board approves a material for use, subsequent reviews and approvals should be only rarely necessary. If the use of the material for a specific purpose is so tenuous as to render it unsuitable elsewhere, perhaps it should not be approved at all. This has not been the normal procedure followed by the Board, however. Often, materials are re-reviewed, or re-sent for supplemental TAPs, adding time and draining limited resources further. Second, we presumed the first approval to be consistent with existing approvals by FDA, again rendering subsequent reviews unnecessary. However, while FDA permits calcium propionate as a GRAS preservative for animal feed, there are no FDA approvals for use to treat milk fever.

In addition, in September 2002, the Board approved potassium sorbate as a mold inhibitor in feed. While there was some discussion at the May meeting about one feed additive as a liquid and the other in dry, pellet form, it is not clear that the two materials are not substitutes for one another in the uses for which they were approved. It should be clear from the Board's decision process and discussion whether both are necessary because their form dictates their use. NOP should not have to assume there is a unique difference that justifies both being added to the list for the same purpose.

We understand that some Board members believe the October 2003 meeting may be less than productive if there are not sufficient materials to discuss. We do not agree. First, we believe the Board should have a very thoughtful discussion on all materials scheduled for consideration. Second, we believe there will be plenty to tackle inasmuch as we will be returning all materials recommendations from the May 2003 meeting for further clarification, explanation, and justification by the NOSB. Furthermore, we want to add this topic – Materials Review, Evaluation, & Determination – to the October agenda. We believe that the NOSB and NOP must concur on the appropriate process for evaluating and approving materials to amend the National List so that users of these materials are fully informed and can adjust their practices accordingly.

Within the next few weeks, we will provide our draft template to evaluate the criteria, along with suggested benchmarks for evaluating adverse impacts of materials. We ask that as Chair of the Board, you discuss this communication and the forthcoming template with the full Board at your earliest convenience. If you have any questions or other matters to discuss, please contact us.

United States Department of Agriculture
Agricultural Marketing Service
STOP 0264 Room 2510–S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0264

August 14, 2003

TO: The National Organic Standards Board

FROM: Barbara C. Robinson
Deputy Administrator Barbara C. Robinson

SUBJECT: Federal Advisory Committees and Information Collection

A questionnaire seeking opinions on the dairy herd replacement language of the National Organic Program (NOP) final regulations was recently circulated to some or all of the USDA-accredited certifying agents. The letter which accompanied the questionnaire was printed on official letterhead stationary of the National Organic Standards Board (NOSB), and asks that certifying agents please circulate the letter and questionnaire to all of their dairy producer clients. The questionnaire includes the following disclaimer at the top of the page: "This is not an official USDA survey."

This memorandum reminds the NOSB that all collections of information by agencies or on their behalf must comply with Federal regulations (5 CFR 1320) that implement the Paperwork Reduction Act (44 USC 35). Not incidentally, a Federal advisory committee is included in these regulations, since its primary purpose is in advising the Secretary on matters for which the Secretary requests information. Members of advisory committees, appointed by the Secretary of Agriculture, are bound by the Federal Advisory Committee Act, the Government in the Sunshine Act and the Paperwork Reduction Act, and therefore, the regulations implementing those statutes. The Office of Management and Budget (OMB) was delegated authority by the Congress to oversee all executive branch agencies' compliance with these laws and regulations.

Soliciting information through unofficial questionnaires is not allowed and has the unintended consequence of admitting bias into the agency's public notice and comment rulemaking process. Therefore, agencies are required not to use the results of such information collections in order to avoid the appearance of bias or pre-selection of an outcome. Notwithstanding the desire of NOP to collect factual information regarding compliance issues, the method by which such information is collected must follow existing Federal regulations. Failure to obtain approval from OMB constitutes a collection violation that the Department must address when OMB performs its annual review to Congress of executive branch compliance with the Paperwork Reduction Act.